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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,100	04/05/2001	Chung Shih	T8418.NP	5014

20551 7590 11/20/2002

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EXAMINER
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DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/827,100	SHIH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert M DeWitty	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 31 October 2002.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) 6,15-39,47 and 48 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-5,7-14,40-46 and 49-56 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 1-56 are pending in the instant application. Acknowledgement is made of Applicant's election of invention, Group I, claims 1-14, 40-47, and 49-56 and the Election of Species.

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that if Group I were to issue and Group II were to issue, this would be problematic because the groups would contain the same independent claim. This is not found persuasive because the restriction was made based on the fact that claims 15-19 are dependent on claim 1. Thus, it is understood by the examiner that the protein in claim 1 would have different meanings for claims 15-19 (the protein being a plurality) and Group I (the protein not being drawn to a plurality).

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7-8, 10, 12, 14, 40-46, 49, 51, 53, 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (U.S. Pat. No. 5,891,478).

Johnson et al. is directed to a composition for sustained release of biologically active hGH (abstract). Stabilized hGH comprises active hGH complexed with a metal cation; the stabilized hGH is in particulate form (col. 2, lines 37-42). A preferred metal cation used to stabilize hGH is  $Zn^{+2}$  (col. 2, lines 55-58). The molar ratio of metal cation component to hGH is 4:1 to about 100:1 (col. 2, lines 51-54). In forming the composition, stabilized hGH is dispersed in a polymer solution (col. 4, lines 63-67). A polymer suitable for the sustained release composition must be biocompatible (col. 3, lines 20-22). Suitable polymers may be copolymers. Further, the terminal functionalities of the polymer can be blocked (col. 3, lines 39-43). In one embodiment, a hGH sustained release composition contains from about 0.01% to about 50% of stabilized hGH particles (col. 4, lines 7-10).

3. Claims 1, 5, 7-9, 40, 46, 49, 50, 52-56 are rejected under 35 U.S.C. 102(b) as being anticipated by DePrince et al. (U.S. Pat. No. 4,765,980).

DePrince teaches methods for stabilization of porcine growth hormone (col. 2, lines 16-17). The growth hormone can be in the form of a metal complex  $Zn-pGH$  (col. 2, lines 58-61). The stabilized growth hormone can be administered via an implant device (col. 2, lines 30-32). The implantable delivery device can be made of materials that are biologically compatible with body fluids, tissues, and organs (col. 4, lines 26-40). Because DePrince teaches a Zn complex (limitation of instant claim 5), attached to a growth hormone (limitation instant claim 7) which can be used in an implant (limitation instant claim 9), as well as methods for preparing the implant device (limitation instant claim 40), the instant invention is anticipated.

***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7-13, 55, 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 12, 18-21, 24, and 25 of U.S. Patent No. 6,287,588. Although the conflicting claims are not identical, they are not patentably distinct from each other because the \*\*588 patent it would have been within the skill on one in the art because \*\*588 clearly teaches a biocompatible phase, microparticles, and an agent. It is the examiner's position that the biocompatible phase corresponds to the biocompatible matrix of the instant invention, the microparticles correspond to the biocompatible particles of the instant invention, and the agent corresponds to the protein or peptide of the instant invention, such agent further being defined in claims 20 and 21.

Mentionable prior art not relied upon include Brodbeck et al. (U.S. Pat. No. 6,130,200) which teaches compositions for administering by implantation a beneficial

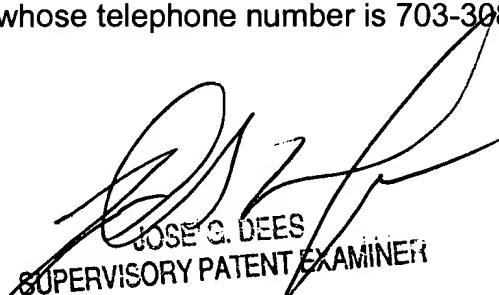
agent, the compositions including a biocompatible polymer; and Cunningham et al. ("Dimerization of Human Growth Hormone by Zinc") which teaches that Zn<sup>2+</sup> may modulate the release of growth hormone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD  
November 17, 2002

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER

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